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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,541	04/04/2007	Friedhelm Schonfeld	BOUL 3507	2502

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1775

NOTIFICATION DATE	DELIVERY MODE
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11/29/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,541	<b>Applicant(s)</b> SCHONFELD ET AL.	
	<b>Examiner</b> WILLIAM H. BEISNER	<b>Art Unit</b> 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 30-58 is/are pending in the application.
- 4a) Of the above claim(s) 52-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/4/07</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, Claims 30-51, in the reply filed on 9/7/2010 is acknowledged.
2. Claims 52-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/7/2010.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

4. The information disclosure statement filed 4/4/2007 has been considered and made of record.

### ***Claim Objections***

5. Claims 52-58 are objected to because of the following informalities: The status identifiers of claims 52-58 should be "(withdrawn)" rather than "(previously presented)". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 30-43 and 45-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Pourahmadi et al.(US 6,440,725).

With respect to claim 30, the reference of Pourahmadi et al. discloses an integrated lab-on-a-chip diagnostic system (See Figure 2) that includes an inlet (103) for a fluid sample, a lysis unit (119) for lysis of cells in the fluid sample; a nucleic acid extraction unit (122) for extraction of nucleic acids from the cells; a reservoir (109) containing a lysis fluid; a reservoir (127) containing an eluent for removing nucleic acids collected in the nucleic acid extraction unit (122); wherein the sample inlet (103) is in fluid communication with the lysis unit (119); wherein the lysis unit (119) is in fluid communication with the nucleic acid extraction unit (122); wherein the reservoir (109) containing lysis fluid is in fluid communication with the lysis unit (119); and wherein the reservoir (127) containing eluent is in fluid communication with the nucleic acid extraction unit (122). Claim 30 further requires that the device includes a single pump capable of introducing sample or air into the sample inlet (103) that is also used to drive the fluid flow within the whole device and requires that the reservoir (109) containing lysis fluid and the reservoir containing an eluent (127) are in fluid communication with the sample inlet. The reference of Pourahmadi et al. discloses that an external pump device can be used to control the movement of fluids within the device (See column 3, line 65, to column 4, line 4, and column

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8, lines 50-55). When using an external pump device to control the fluid flow within the system as disclosed by the reference of Pourahmadi et al., the resulting manifold system would inherently provide fluid communication between a single external pump and each of the chambers for providing the required flow in the device and would result with the lysis fluid reservoir (109) and the eluent fluid reservoir (127) being in fluid communication with the sample inlet via the pumping manifold system. Also note the use of valves (123) within the device.

With respect to claim 31, the device of Pourahmadi et al. also includes a nucleic acid reaction unit (141,143) in fluid communication with the extraction unit (122).

With respect to claim 32, the device of Pourahmadi et al. also includes a waste unit (139) in fluid communication with the lysis unit (119) and extraction unit (122).

With respect to claim 33, the device of Pourahmadi et al. also includes a reservoir (125) containing a washing solvent in fluid communication with the extraction unit (122).

With respect to claims 34-38, either of the reservoirs (125 or 127) are structurally capable of holding and/or functioning in the manner required of claims 34-37. Note statements of intended use carry no patentable weight in apparatus type claims. Also note that the contents of the chambers cannot patentably distinguish the device over other prior art structures since the contents of the chambers is considered material worked on by the device (See MPEP 2115).

With respect to claims 39-42, the lysis unit (119) includes a filter device (See column 9, lines 10-15).

With respect to claim 43, the device of Pourahmadi et al. can include a heater for heating the contents of the lysis unit or extraction unit (See column 10, lines 10-17, and column 16, lines 19-22).

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With respect to claim 45, the device of Pourahmadi et al. can include glass beads (50) within the extraction unit (See column 30, lines 61-67).

With respect to claim 46, the device of Pourahmadi et al. discloses that the extraction unit can include electrodes for applying a voltage so as to attract and/or elute nucleic acid (See column 26, lines 19-27).

With respect to claim 47, the reference of Pourahmadi et al. discloses the use of platinum as an electrode material (See column 20, lines 60-64).

With respect to claim 48, the device of Pourahmadi et al. is structurally capable of extracting nucleic acids from any of the sampled listed in the claim. Note statements of intended use carry not patentable weight in apparatus-type claims.

With respect to claims 49 and 50, the disclosed system of Pourahmadi et al. inherently meets the claim limitations of claims 49 and 50 since it is capable of being used and collecting biological and/or environmental samples (See column 10, line 53, to column 11, line 57).

With respect to claim 51, the device is considered to be disposable in the absence of further positively recited structure.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al.(US 6,440,725).

The reference of Pourahmadi et al. has been discussed above.

With respect to claim 44, while the reference discloses the device of Pourahmadi et al. can include a heater for heating the contents of the lysis unit or extraction unit (See column 10, lines 10-17, and column 16, lines 19-22), the reference is silent with respect to the use of a peltier element.

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The reference of Pourahmadi et al. discloses that the use of Peltier elements is known in the art with respect to the PCR section of the device (See column 20, lines 24-26).

In view of this teaching and in the absence of a showing of unexpected results, it would have been well within the purview of one having ordinary skill in the art to employ a Peltier device to control the temperature of the either the lysing unit or extraction unit as is conventional in the art for controlling the temperature of a reaction zone within a microfluidic device.

### *Conclusion*

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/  
Primary Examiner  
Art Unit 1775**

WHB